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EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,138	DYER, WALLACE K.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-11,13,15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) *15 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4, 7-11, 13, 20-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *5/20/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/05 has been entered. Claims 1, 4, 7-11, 13, 15 and 17-29 were pending. Applicants amended claims 1, 4, 13, 15, 17, 20-23, 28 and 29. No claims were added or canceled. Therefore, claims 1, 4, 7-11, 13, 15 and 17-29 are currently pending. Claims 15 and 17-19 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim. Therefore, claims 1, 4, 7-11, 13 and 20-29 are examined on the merits.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Withdrawn Objections/Rejections

2. The Ersek et al. rejection under 35 U.S.C. § 102(b) is withdrawn in view of Applicants' arguments and/or amendments. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 102

3. Claims 1, 4, 7, 13 and 20-22, 28, 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Bisson (FR 2785811) (Publication date is **May 19, 2000**) (of record).

For ***claims 1, 4, 7, 20-22, 28, 29***, Bisson (see entire document) discloses compositions comprising porous microparticles and/or a suspension agent used for soft tissue augmentation (e.g., see Bisson translation, page 1, paragraph 1; see also claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"), which anticipates the claimed invention. For example, Bisson discloses biocompatible micronized textured polyethylene particles with a size greater than 60 microns (e.g., see Bisson translation, page 4, paragraphs 1-2, "The material which constitutes the microparticles will be ... polyethylene"; see also claim 3, "Composition ... characterized in that the particles have a spherical or ovoid shape with a diameter greater than approximately 10 μm, preferably 30-100 μm [i.e., these are "micronized" particles]"). In addition, Bisson discloses a "textured" microparticles (e.g., see Bisson translation, claim 1, "Composition comprising porous microparticles [i.e., has a "textured" surface] whose pore diameter excludes the penetration of figured elements having a molecular weight of more than 1000 kilodalton"). Bisson also discloses "high density" polyethylene (e.g., see page 3, "For example, one can use a polymer chosen from ... polyethylene, preferably 'high density'"). Finally, Bisson discloses a physiological carrier (e.g., Bisson translation, claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"; see

also page 5, see also claim 12, "Composition according to any one of Claims 8-10, characterized in that the suspension agent is a liquid or a gel chosen from the polymers of substituted or unsubstituted acrylamide, of vinylpyrrolidone, of hydroxyalkyl acrylate, or the copolymers of substituted or unsubstituted acrylamide and of another molecule bearing a positive electric charge, such as a quaternary ammonium cationic monomer"). The examiner also notes that the above composition is used for "soft tissue augmentation" and is explicitly injected into soft tissue (e.g., see page 1, paragraph 1, "The present invention concerns compositions comprising porous microparticles and/or a suspension agent ... usable for implantation in a tissue, in particular to increase the volume of this tissue ("soft tissue augmentation"), notably in view of correcting in a lasting manner a deficit in the appearance or the function of this tissue or organ").

Response

4. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue, "An Applicant may establish prior invention by showing facts that the Applicant reduced to practice prior to the effective date of the reference ..." and further submit a 37 C.F.R. §1.131 declaration by Wallace K. Dyer and a supporting declaration by Stephen Perkins (e.g., see 8/2/05 Response, page 11; see also declarations by Dyer and Perkins).

This is not found persuasive for the following reasons:

The declarations filed on 8/2/05 under 37 CFR 1.131 have been considered but are ineffective to overcome the Bisson reference. "The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. *In re Tanczyn*, 347 F.2d 830, 146 USPQ 298 (CCPA 1965) (Where applicant claims an alloy comprising both nitrogen and molybdenum, an affidavit showing applicant made an alloy comprising nitrogen but not molybdenum is not sufficient under 37 CFR 1.131 to overcome a rejection under 35 U.S.C. 103 based on the combined teachings of one reference disclosing an alloy comprising nitrogen but not molybdenum and a second reference disclosing an alloy comprising molybdenum but not nitrogen)" (e.g., see MPEP § 715.02). Here, Applicant's declarations set forth the use of expanded polytetrafluoroethylene (e-PTFE) to show possession of the claimed invention. However, Applicants do not assert that e-PTFE falls within the scope of the currently claimed "high density" polyethylene. In addition, the scope of what constitutes a "high density" polyethylene is not clear (e.g., see 35 U.S.C. 112, second paragraph rejection below). Therefore, Applicants have failed to establish possession of the currently claimed invention as required by MPEP § 715.02 (see above).

Accordingly, the 35 U.S.C. § 102(a) rejection cited above is hereby maintained.

New Rejections

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4, 7-11, 13 and 20-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claims *1, 13, 20-23, 28 and 29***, the term "high density" polyethylene is vague and indefinite in view of Applicant's declarations. For example, Applicant states that High Density Polyethylene (HDPE) has an elastic modulus between 1068-1380 MPa as disclosed by the "Handbook of Polyethylene, structures, Properties and Applications" by Andrew J. Peacock (e.g., see 8/2/05 Response, page 8; see also Peacock reference). However, Applicants later implicitly assert (via a 1.131 declaration) that expanded polytetrafluoroethylene (e-PTFE) particles falls within the scope of a high-density polyethylene (e.g., see Dyer declaration under 37 C.F.R. § 1.131, paragraph 3 wherein expanded polytetrafluoroethylene particles in a polyvinylpyrrolidone solution are used to show possession of the currently claimed high density polyethylene particles). However, Catanese et al. disclose that e-PTFE particles only possess an elastic modulus of ~ 40-50 MPa, which is << that the required 1068-1380 MPa (e.g., see Catanese, J.; Cooke, D.; Maas, C.; Pruitt, L. "Mechanical Properties of Medical Grade Expanded Polytetrafluoroethylene: The Effects of Internodal Distance, Density and Displacement Rate" *J. Biomed. Mater. Res. (Appl Biomater)* **1999**, *48*, 187-192, especially Table 2). Likewise, Stevens disclose a modulus value for Applicant's elected polytetra-fluoroethylene to be closer to low density than high density polyethylene (e.g., see Stevens, M. P. Polymer Chemistry an Introduction. Third Edition. New York: Oxford Press, Inc. **1999**, pages 105, especially Table 4.1). Consequently, the metes and bound of

the claimed invention cannot be determined. Therefore, claims 1, 13, 15, 20-23, 28, 29 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4, 7-11, 13 and 20-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

Claim 1, 13, 20-23, 28 and 29 were amended in the 8/2/05 Response to recite the limitation "high density" polyethylene. However, the Examiner cannot find support for these amendments. In fact, Applicants state, "[we] have discovered novel compositions of injectable material suitable for tissue replacement that are biocompatible, moldable, mechanically stable, and have a consistency similar to the tissue that it replaces" (e.g., see specification, paragraph 50), which "teaches away" from the use of inflexible materials (i.e., high density polyethylene) with soft tissue. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02. Therefore, claim 1, 13, 15, 20-23, 28, 29 and all dependent claims are rejected for containing new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 4, 7-11, 13, and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. (US Patent No. 5,336,263) (Date of Patent is **August 9, 1994**) (of record) and Catanese et al. (Catanese, J.; Cooke, D.; Maas, C.; Pruitt, L. "Mechanical Properties of Medical Grade Expanded Polytetrafluoroethylene: The Effects of Internodal Distance, Density and Displacement Rate" *J. Biomed. Mater. Res. (Appl Biomater)* **1999**, *48*, 187-192, especially Table 2) as evidenced by the Polymer Products from Aldrich Reference (of record) (**Please note**: that MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent).

For ***claims 1, 4, 7 and 22***, Ersek et al. (see entire document) disclose biphasic compositions for the treatment of urological and gastric fluid disorders (e.g., see abstract), which anticipate claims 1, 4, 7 and 22. For example, Ersek et al. disclose biocompatible micronized textured polyethylene particles having a size greater than sixty microns (e.g., see abstract; see also column 3, lines 23-26, "The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 80 > 60]"; see also paragraph bridging columns 5-6, "For soft tissue ... [a] desirable

material for the textured particles ... [is] polyethylene"). In addition, Ersek et al. disclose various physiological carriers including polyvinylpyrrolidone (e.g., see column 3, lines 37-53, "Examples of appropriate physiologic vehicles [i.e., physiological carriers] are ... polyvinylpyrrolidones").

The Examiner further notes that the limitations in the preamble claiming a mechanically stable biphasic injectable composition for "soft tissue augmentation" and in the last line of the claim "wherein the composition is injected into soft tissue" are *intended use* recitations that merely recite the purpose of the process or the intended use of the structure and thus have not been accorded any patentable weight (e.g., see MPEP 2111.02: A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481. Also, "[i]n a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art." *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In addition, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are

the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01.

For ***claims 8-11 and 24-27***, Ersek et al. do not disclose any K values for the polyvinylpyrrolidones (PVP) used therein; however, Ersek et al. disclose a polyvinylpyrrolidone with a molecular weight of 13,700 (e.g., see Example 2), which would inherently possess a K between 13-19 (e.g., see Polymer Products from Aldrich Reference, page 5, Table III, citing "GAF(ISP) Technical Bulletin 2302-203 SM-1290, "PVP polyvinylpyrrolidone Polymers", wherein the relationship between the K-value and the molecular weight and/or intrinsic viscosity of PVP has been calculated and clearly shows that that the K value for the PVP is in the range of 13-19 because 13,700 M_w falls within the ~ 12,000 M_w range). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claims 13 and 23***, Ersek et al. disclose an "approximately" 3:2 ratio by weight carrier to particles (e.g., see column 9, lines 25-27, "The mixture utilized was approximately 38% by weight of the polymer particles and 62% of the gel material [i.e., 62% gel / 38% particles = 1.6, which is "approximately" 1.5 or a 3/2 ratio by weight]"; see also paragraph bridging columns 5-6 wherein Ersek et al. disclose that polyethylene

can be substituted for poly(dimethylsiloxane) disclosed in Example I; see also column 8, lines 61-63 wherein Ersek et al. disclose that this "ratio" represents a mere design choice).

For ***claims 20-21 and 28-29***, Ersek et al. disclose particles having a size greater than 100 microns (e.g., see column 3, lines 23-26, "The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 600 > 100]").

The prior art teachings of Ersek et al. differ from the claimed invention as follows:

For ***claim 1***, Ersek et al. are deficient in that they do not specifically teach the use of "high density" polyethylene. The reference is silent on the issue. Ersek et al. only teach the use of polyethylene without specifying its density (e.g., see

However, Catanese et al. teach the following limitations that are deficient in Ersek et al.:

For ***claim 1***, Catanese et al. (see entire document) teach the use of Applicants' preferred expanded polytetrafluoroethylene (e-PTFE) for use in medical implants including plastic and reconstructive surgery (e.g., see Catanese et al., abstract; see also Introduction; see also 35 U.S.C. 112, second paragraph rejection above).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make the biphasic compositions as taught by Ersek et al. with the e-PTFE as taught by Catanese et al. because Catanese et al. explicitly state that e-PTFE is useful as a tissue implant including "soft" tissue as disclosed by Ersek et al. (e.g., see

Catanese et al., page 187, column 2, last paragraph, "For these medical applications e-PTFE is the standard choice for a number of reasons. PTFE is a completely fluorinated homopolymer that is highly nonreactive and nontoxic when implanted in biological tissues"; see also page 187, column 1, last line, "Recently, e-PTFE has found important applications in soft tissue replacement and biofixation for plastic and reconstructive surgery"), which is exactly what the biphasic compositions disclosed by Ersek et al. are being used for (e.g., see Ersek et al., Detailed Description of the Invention, "The above-referenced copending application relates to an improved micro-implantation method ... [for] tissue defects in reconstructive surgery procedures. The tissues to be augmented exhibit varying degrees of softness"; see also claim 1; see also example 1). Furthermore, one of ordinary skill in the art would have been motivated to use the e-PTFE because Catanese et al. state that it is "non-toxic" and porous, provides a "better modulus match for soft biological tissue" application and "encourages ingrowth" of tissue and hence moderate levels of biofixation (see Catanese et al., paragraph bridging pages 187 and 188). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Catanese et al. teach that e-PTFE has been widely employed in clinical applications (see Catanese et al., Introduction). In addition, Ersek et al. state that polyethylene and polytetrafluoroethylene fall within the scope of their claimed invention (e.g., see also column 3, lines 23-26, "The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 80 > 60]"; see also paragraph bridging columns 5-6, "For soft tissue ... [a] desirable material for the textured particles ... [is] polyethylene"; see also column 8, paragraph 2, "It will be

appreciated that textured spheroids of the class contemplated for use in the present invention may be ... fabricated from ... polytetrafluoroethylene").

Response

8. To the extent that Applicant's arguments to the previous Ersek et al. rejection under 35 U.S.C. § 102(b) can be applied to the 35 U.S.C. § 103(a) rejection above, the following points are noted.

Applicants argue, "Ersek teaches implantation of particles that have physical characteristics that mimic the augmentation site. Further, there is no teachings in Ersek of Applicants' currently claimed invention comprising compositions and methods of implantation into soft tissues of a composition comprising high density polyethylene particles" and further go on to explain the differences between high density and low density polyethylene (e.g., see 8/2/05 Response, page 6-7).

This is not found persuasive for the following reasons:

The combined teachings of Ersek and Catanese et al. teach Applicants' preferred e-PTFE (see above). In addition, nonpreferred embodiments constitute prior art (e.g., see MPEP § 2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)"). Here, the passages cited by Applicants represent merely "preferred" embodiments (e.g., see Ersek, columns 5-6, "For a soft tissue, a soft elastomer such as silicone rubber is a desirable [i.e., preferred] material for the textured particles; see also column 8, lines 26-29, " fabrication of the

spheroids from a malleable polymer material such as a silicone rubber is preferred"). Ersek et al. also teach that a wide range of physical properties can be used (e.g., see Detailed Description of the Invention, "The tissues to be augmented exhibit varying degrees of softness"). Furthermore, the "metes and bound" of the claimed invention cannot be determined (e.g., see 35 U.S.C. 112, second paragraph above). Thus, the cited passages do not constitute a "teaching away" as purported by Applicants.

Accordingly, the 35 U.S.C. § 103(a) rejection cited above is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
October 24, 2005

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